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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/698,354 | 10/30/2003 | David James Rawson | PC25373A | 1622 |
| | 7590 09/13/2007 CORPORATION | EXAMINER | | |
| GLOBAL PAT | ENT DEPARTMENT | ROYDS, I | ROYDS, LESLIE A | |
| POST OFFICE BOX 1027 ST. LOUIS, MO 63006 | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/13/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| 1) Responsive to communication(s) filed on 25 June 2007. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 11-26 is/are pending in the application. 4a) Of the above claim(s) 15,16 and 18-25 is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 11.12,14.17 and 26 is/are rejected. 7) Claim(s) 13.26 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | Application No. | Applicant(s) | | | | |
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| Leslie A. Royds 1614 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION is the Communication of the Cover of the | | 10/698,354 | RAWSON, DAVID JAMES | | | | |
| - The MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of immary be availated under the provisions of 37 CFR 1306, in no event, towers, tray a reply the invertible of the provision of 37 CFR 1306, in no event flowers, they are the first in the provision of Claims 4) □ This action is FINAL. 2b) □ This action is non-final. 3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) □ Claim(s) 11-26 is/are pending in the application. 4a) Of the above claim(s) 15.16 and 18-25 is/are withdrawn from consideration. 5) □ Claim(s) 11-26 is/are allowed. 6) □ Claim(s) 11-26 is/are allowed. 6) □ Claim(s) 13.26 is/are objected to. 8) □ Claim(s) 13.26 is/are objected to by the Examiner. Application Papers 9) □ The specification is objected to by the Examiner. Application Papers 9) □ The drawing(s) filed on | Oπice Action Summary | Examiner | Art Unit | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of liner may be available under the provisions of 37 CPR 1.136(a), line event, however, may a ratery be timely filed. Extensions of liner may be available under the provisions of 37 CPR 1.136(a), line event, however, may a ratery be timely filed. Extensions of liner may be available under the provisions of 37 CPR 1.136(a), line event, however, may a ratery be timely filed. Extensions of the many provision in the provision of 37 CPR 1.136(a), line event, however, may are the maining date of his communication. Failure to reply when the set or cutended period for reply will, by statute, cause the application to become AdANDONED (36 U.S. € 9 133). Any graphy received by the Middle of the the there environed after the communication, even if simely filed. may reduce any control term department. Set 97 CPR 1.134(b). Status 1) □ Responsive to communication(s) filed on 25 June 2007. 2a) □ This action is FINAL. 2b) □ This action is non-final. 3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) □ Claim(s) 11.26 is/are pending in the application. 4a) Of the above claim(s) 15.16 and 18-25 is/are withdrawn from consideration. 5□ □ Claim(s) 11.12.14.17 and 26 is/are rejected. 7) □ Claim(s) 11.12.14.17 and 26 is/are rejected. 10 □ The drawing(s) filed on | | | | | | | |
| WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of them may be available under the provision of 37 ERT 1136(a). In no event, however, may a reply be timely fled after 10X (6) MONTHS from the mailing date of this communication. Failing to require whether the mailing date of this communication. Failing to require whether the mailing date of this communication. Failing to require whether the mailing date of this communication. Failing to require them adjustment. See 37 CFR 1.704(b). Status 1) □ Responsive to communication(s) filed on 25 June 2007. 2a) □ This action is FINAL. 2b) □ This action is non-final. 3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) □ Claim(s) 11.26 is/are pending in the application. 4a) Of the above claim(s) 15.6 and 18-25 is/are withdrawn from consideration. 5) □ Claim(s) 11.26 is/are allowed. 6) □ Claim(s) 11.21.417 and 26 is/are rejected. 7) □ Claim(s) 11.22 is/are objected to by the Examiner. 9) □ The specification is objected to by the Examiner. 10) □ The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. Application Papers 9) □ The specification is objected to by the Examiner. 10 □ The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. Application Papers 9) □ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12 □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) □ All b) □ Some * ○ □ None of . 1. □ Certified copies of the priority documents have been received in Application No application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | · · · · · · · · · · · · · · · · · · · | | | | | | |
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| a) ☐ All b) ☐ Some * c) ☐ None of: 1. ☐ Certified copies of the priority documents have been received. 2. ☐ Certified copies of the priority documents have been received in Application No 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) ☑ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) 1. ☐ Certified copies of the priority documents have been received in Application No 4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date 5) ☐ Notice of Informal Patent Application | Priority under 35 U.S.C. § 119 | | | | | | |
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DETAILED ACTION

Claims 11-26 are presented for examination.

Applicant's Amendment filed June 25, 2007 has been received and entered into the present application.

Claims 11-26 are pending. Claims 11-14, 17 and 26 are under examination and claims 15-16 and 18-25 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 11, 13 and 17 are amended.

Applicant's arguments, filed June 25, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the present application.

Applicant's Request for Rejoinder of Present Claims 17 and 26

Applicant requests rejoinder of claims 17 and 26 as noted at page 8 of the remarks filed June 25, 2007. In view of the fact that search and examination of the instant claims has been extended beyond the elected species of (2S,4S)-4-(3-fluorobenzyl)-pyrrolidone-2-carboxylic acid as noted at page 2 of the previous Office Action dated February 26, 2007 to include compounds of generic formula (Ia), claims 17 and 26, each directed to the species of (2S, 4S)-4-(3-chlorophenoxy)-pyrrolidine-2-carboxylic acid, read on this set of species now under examination.

Objections to the Claims (New Grounds of Objection)

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Claim 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 17, since they both encompass identical embodiments of the claimed invention. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. Please reference MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14, 17 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kyle et al. (U.S. Patent No.5,385,889; 1995), already of record, for the reasons of record set forth at page 6 of the previous Office Action dated February 26, 2007, of which said reasons are herein incorporated by reference, in light of newly cited IUPAC Compendium of Chemical Terminology ("Cis-Trans Isomers", 1997), cited to show a fact.

Present claims 17 and 26 are properly included in the present rejection because Kyle et al. teaches the preparation of an intermediate chemical entity and its use to prepare a bradykinin antagonist peptide,

which has the following chemical formula (col.6, 1.34-44 and col.20, 1.35-61):

, wherein

R is an aryl group, a substituted aryl group or an araalkyl group, X is oxygen (col.20, 1.49-52) and R2 and R3 are each hydrogen (col.20, 1.56-69). Kyle et al. defines "aryl" groups as benzene, phenyl or naphthyl and "substituted aryl" groups as a substituted aromatic ring with nitro substitution or halogen substitution

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(col.20, l.66-col.21, l.2). In view of such a teaching, Kyle et al. clearly provides for compounds wherein the substituted aryl group is a phenyl group substituted, at any available position, with a halogen. The very teaching of a "halogen" would have placed the use of any known halogen (including chlorine as presently claimed) well within the possession of the public due to the extremely limited size of the genus (i.e., a genus of only four members: fluorine, chlorine, bromine, iodine).

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the compounds presently claimed are *cis*-L-proline derivatives and the compounds of the cited '889 patent to Kyle et al. are proline derivatives with a D-configuration, not an L-configuration as presently claimed. Applicant alleges that, in view of this fact, Kyle et al. fails to anticipate each and every element of the claimed compounds.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, Applicant's attention is directed to column 20, lines 39-40, of Kyle et al. which expressly teaches that the intermediate compound is in the D-configuration, either the *cis-* or *trans-* structure.

$$\begin{array}{c}
RN \\
N \\
C \\
Q
\end{array}$$

wherein the trans- structure has the formula

(i.e., the -XR moiety and the -COOH

moiety are found in different planes as evidenced by the wedge bond connecting the -XR moiety to the pyrrolidine ring and the hashed bond connecting the -COOH moiety to the pyrrolidine ring).

Though Kyle et al. does not provide a structural depiction of the *cis*-structure, one of skill in the art at the time of the invention would have recognized that such a structure would have been identical to that provided *supra*, but for the fact that the carboxylic acid moiety at the 2-position of the pyrrolidine ring would have been found in the same plane as the –XR moiety at the 4-position of the pyrrolidine ring

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(i.e., both the -XR moiety and the -COOH moiety would be connected to the pyrrolidine ring via a wedge bond). Such a conclusion is supported by the IUPAC Compendium of Chemical Terminology, which teaches that, for *cis*-isomers, the atoms are on the same side (i.e., in the same plane of reference) whereas *trans*-isomers have the atoms on opposite sides (i.e., not in the same plane of reference).

Accordingly, Kyle et al. does, in fact, clearly provide for compounds with a stereochemical configuration identical to that presently claimed by its very teaching of the *cis*-configuration of the intermediate compound. Despite the fact that the reference does not provide a structural depiction of the *cis*-isomer, one of ordinary skill in the art would have readily recognized that the *cis*-isomer would have the same atom connectivity as the *trans*-isomer, but for the fact that the –XR moiety and the –COOH moiety would be oriented in the same direction (i.e., in the same reference plane), as opposed to the *trans*-isomer, where the –XR moiety and the –COOH moiety would be oriented in opposing directions (i.e., in different reference planes).

Though Applicant alleges that the compounds of Kyle et al. and those of the present claims further differ on the grounds that the presently claimed compounds are in an L-proline configuration and the compounds of Kyle et al. are in a D-proline configuration, it is noted that neither Applicant's claims, nor the instant specification, specify that the compounds are L-proline derivatives and not D-proline derivatives. In other words, Applicant's argument that the reference to Kyle et al. fails to show certain features of Applicant's invention (i.e., that the compounds are L-proline derivatives and not D-proline derivatives), it is noted that this feature upon which Applicant relies (i.e., L- versus D-configuration) is not recited in the rejected claim. Furthermore, even if the specification *did* specify that the presently claimed compounds were in an L-configuration and not a D-configuration, it is noted that, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please reference *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Moreover, even if Applicant had specifically claimed the L-proline configuration (which is not

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conceded by the Examiner), the compounds disclosed in Kyle et al. would still anticipate the presently claimed compounds, despite the fact that Kyle et al. refers to the structure as being in a D-configuration because Kyle et al. explicitly teaches both the cis- and trans- isomers of the same molecule with identical atom connectivity and clearly provides for circumstances wherein the -XR moiety and the -COOH moiety are either in the same reference plane (i.e., cis) or in opposing planes (i.e., trans). In other words, despite the fact that Kyle et al. may refer to this configuration as a "D" configuration, where Applicant alleges that it is, in fact, an L-configuration, the very teaching of a compound identical to that claimed in atoms, atom connectivity, and spatial arrangement of the atoms, clearly supports the conclusion of anticipation because Kyle et al. provides for each and every element of the claimed compounds.

For these reasons, and those previously made of record at page 6 of the previous Office Action dated February 26, 2007, rejection of claims 14, 17 and 26 is proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-12, 14, 17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kyle et al. (U.S. Patent No. 5,385,889; 1995), already of record, for the reasons of record set forth at pages 6-8 of the previous Office Action dated February 26, 2007, of which said reasons are herein incorporated by reference, in light of newly cited IUPAC Compendium of Chemical Terminology ("Cis-Trans Isomers", 1997), cited to show a fact.

Present claims 17 and 26 are properly included in the present rejection because Kyle et al. teaches the preparation of an intermediate chemical entity and its use to prepare a bradykinin antagonist peptide.

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which has the following chemical formula (col.6, 1.34-44 and col.20, 1.35-61):

, wherein

R is an aryl group, a substituted aryl group or an araalkyl group. X is oxygen (col.20, 1.49-52) and R2 and R3 are each hydrogen (col.20, 1.56-69). Kyle et al. defines "aryl" groups as benzene, phenyl or naphthyl and "substituted aryl" groups as a substituted aromatic ring with nitro substitution or halogen substitution (col.20, 1.66-col.21, 1.2). In view of such a teaching, Kyle et al. clearly provides for compounds wherein the substituted aryl group is a phenyl group substituted, at any available position, with a halogen. The very teaching of a "halogen" would have placed the use of any known halogen (including chlorine as presently claimed) well within the possession of the public due to the extremely limited size of the genus (i.e., a genus of only four members: fluorine, chlorine, bromine, iodine).

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that the compounds presently claimed are *cis*-L-proline derivatives and the compounds of the cited '889 patent to Kyle et al. are proline derivatives with a D-configuration, not an L-configuration as presently claimed. Applicant further submits that Kyle fails to provide any hint or suggestion that proline derivatives with a D-configuration would themselves have therapeutic utility, let alone that derivatives with the L-configuration would demonstrate activity as alpha-2-delta ligands. Applicant alleges that biological activity of compounds may be radically altered by optical isomerism such that compounds that are active in the L-configuration are frequently inactive in the D-configuration, such as with amino acids. Applicant further alleges that the '889 patent fails to teach how to make the compounds instantly claimed and that the closest compound taught in this reference is an intermediate, not a final product, and in an optical form that one of skill in the art would "believe likely to be biologically inactive" (Applicant's remarks, p.12).

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Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

First, Applicant's attention is directed to column 20, lines 39-40, of Kyle et al. which expressly teaches that the intermediate compound is in the D-configuration, either the *cis*- or *trans*- structure.

wherein the trans- structure has the formula

(i.e., the -XR moiety and the -COOH

moiety are found in different planes as evidenced by the wedge bond connecting the -XR moiety to the pyrrolidine ring and the hashed bond connecting the -COOH moiety to the pyrrolidine ring).

Though Kyle et al. does not provide a structural depiction of the *cis*-structure, one of skill in the art at the time of the invention would have recognized that such a structure would have been identical to that provided *supra*, but for the fact that the carboxylic acid moiety at the 2-position of the pyrrolidine ring would have been found in the same plane as the –XR moiety at the 4-position of the pyrrolidine ring (i.e., both the –XR moiety and the –COOH moiety would be connected to the pyrrolidine ring via a wedge bond). Such a conclusion is supported by the IUPAC Compendium of Chemical Terminology, which teaches that, for *cis*-isomers, the atoms are on the same side (i.e., in the same plane of reference) whereas *trans*-isomers have the atoms are on opposite sides (i.e., not in the same plane of reference).

Accordingly, Kyle et al. does, in fact, clearly provide for compounds with a stereochemical configuration identical to that presently claimed by its very teaching of the *cis*-configuration of the intermediate compound. Despite the fact that the reference does not provide a structural depiction of the *cis*-isomer, one of ordinary skill in the art would have readily recognized that the *cis*-isomer would have the same atom connectivity as the *trans*-isomer, but for the fact that the –XR moiety and the –COOH moiety would be oriented in the same direction (i.e., in the same reference plane), as opposed to the *trans*-

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isomer, where the -XR moiety and the -COOH moiety would be oriented in opposing directions (i.e., in different reference planes).

Though Applicant alleges that the compounds of Kyle et al. and those of the present claims further differ on the grounds that the presently claimed compounds are in an L-proline configuration and the compounds of Kyle et al. are in a D-proline configuration, it is noted that neither Applicant's claims, nor the instant specification, specify that the compounds are L-proline derivatives and not D-proline derivatives. In other words, Applicant's argument that the reference to Kyle et al. fails to show certain features of Applicant's invention (i.e., that the compounds are L-proline derivatives and not D-proline derivatives), it is noted that this feature upon which Applicant relies (i.e., L- versus D-configuration) is not recited in the rejected claim. Furthermore, even if the specification *did* specify that the presently claimed compounds were in an L-configuration and not a D-configuration, it is noted that, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Please reference *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Moreover, even if Applicant had specifically claimed the L-proline configuration (which is not conceded by the Examiner), the compounds disclosed in Kyle et al. would still render the presently claimed compounds obvious, despite the fact that Kyle et al. refers to the structure as being in a D-configuration because Kyle et al. explicitly teaches both the *cis*- and *trans*- isomers of the same molecule with identical atom connectivity and clearly provides for circumstances wherein the –XR moiety and the –COOH moiety are either in the same reference plane (i.e., *cis*) or in opposing planes (i.e., *trans*). In other words, despite the fact that Kyle et al. may refer to this same configuration as a "D" configuration, where Applicant alleges that it is, in fact, an L-configuration, the very teaching of a compound identical to that claimed in atoms, atom connectivity, and spatial arrangement of the atoms, clearly supports the conclusion of obviousness because Kyle et al. provides for each and every element of the claimed compounds.

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Second, contrary to Applicant's assertions that Kyle et al. fails to teach that the disclosed intermediate product has a therapeutic utility, the reference does, in fact, disclose that this isolated intermediate compound may be used in the preparation of a final bradykinin antagonist peptide product. In other words, the very teaching that the disclosed intermediate product may be further reacted to form a bradykinin antagonist peptide amounts to a clear therapeutic utility to create the final bradykinin antagonist peptide.

Furthermore, regardless of the fact that Kyle et al. may disclosed the compounds of the formula identified *supra* as intermediate products, it remains that such compounds are both *structurally identical* and *stereochemically identical* (i.e., via the teaching of both *cis*- and *trans*- isomers) to those that Applicant has presently claimed within generic formula (Ia). Accordingly, the fact that Kyle et al. does not disclose them as having the alpha-2-delta ligand activity as Applicant has discovered in immaterial to the fact that Kyle et al. has expressly isolated and identified compounds of the identical chemical structure and stereochemical configuration as those presently claimed (see, e.g., present claim 14). Products of identical chemical composition cannot have mutually exclusive properties, so whatever alpha-2-delta ligand activity Applicant has presently attributed to the claimed compounds is necessarily present in the compounds expressly isolated and disclosed by Kyle et al., whether recognized by the patentee or not. Please reference MPEP §2112. In addition, the fact that Applicant's utility may differ from the utility disclosed in Kyle et al. is immaterial to the fact that the reference discloses (1) compounds of the exact and identical chemical (and stereochemical) structure to those presently claimed and (2) a specific and substantial utility for such compounds. In view of such disclosure, Kyle et al. clearly supports the obviousness of the presently claimed invention, absent factual evidence to the contrary.

Third, Applicant's allegation that the "biological activity [of compounds] may be radically altered by optical isomerism, and that compounds that are active in the 'L' configuration are frequently inactive in the 'D' configuration, as in, for example, amino acids" (Applicant's remarks, p.12-13) is not a point

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well taken. Initially, it is noted that, in accordance with the reasoning set forth in *In re Adamson and Duffin*, 125 USPQ 233, one of skill in the art *expects* that individual stereoisomers will differ in physiological/pharmacological activity and toxicity, because living systems are chiral and thus preferentially process certain stereochemical configurations over others (emphasis added). Please reference page 234, para.3 and page 235, para.5. In view of such a teaching, Applicant's allegation that optical isomers will differ in activity is not necessarily disputed. However, Applicant allegation that compounds active in the 'L' configuration "are frequently inactive in the 'D' configuration" is unsupported by any evidence in support of this assertion. Accordingly, such a statement amounts to no more than an allegation without factual support that optical D-isomers are inactive as compared to the optical L-isomer. Please see, e.g., MPEP §716.01(c)[R-2](II), which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716. 718. (CCPA 1965)."

Here, even if Applicant had supported such an allegation with factual support, it is again noted that Kyle et al. explicitly teaches both the *cis*- and *trans*- isomers of the same molecule as presently claimed with identical atom connectivity and clearly provides for circumstances wherein the –XR moiety and the –COOH moiety are either in the same reference plane (i.e., *cis*) or in opposing planes (i.e., *trans*). In other words, despite the fact that Kyle et al. may refer to this same configuration as a "D" configuration, the very teaching of a compound identical to that claimed in atoms, atom connectivity, and spatial arrangement of the atoms (i.e., stereochemical configuration) clearly supports the conclusion that the compounds as taught by Kyle et al. are not, in fact, different from those presently claimed. As a result, whatever differences Applicant alleges would result from the different optical isomers are moot in view of the fact that the compounds taught by Kyle et al. are stereochemically identical to those presently claimed and, thus, would not be expected to result in differences in biological activity.

Fourth, Applicant's allegation that Kyle et al. fails to teach how to make the compounds instantly

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claimed is, in fact, in error, since Kyle et al. expressly discloses representative synthetic schema for preparing the proline derivative residues located at position-7 of the final bradykinin peptide product. Please reference Kyle et al. at col.22, 1.15-col.23, 1.29.

Fifth, Applicant attempts to demonstrate patentable distinction of the instantly claimed compounds over those in Kyle et al. by arguing that the compound disclosed in Kyle et al. is an intermediate and not a final product. However, the relevance of such arguments is unclear. Though Kyle et al. does disclose the proline derivative compound as an intermediate, such a teaching does not negate the fact that Kyle et al. expressly prepared, isolated, further employed and very clearly contemplated such compounds of an identical structure and stereochemical configuration to those presently claimed. As a result, the intermediate nature of the compounds, in the sense that they are the used to prepare a different final product (in this case, a bradykinin antagonist peptide product), fails to detract from the overall teaching of the compounds *per se*. In view of the fact that the compounds of Kyle et al. have a clear, specific and substantial utility, Applicant's arguments that the teaching of such compounds as intermediate compounds is insufficient to support a finding of obviousness is clearly not persuasive.

Lastly, Applicant asserts that the compounds of Kyle et al. are in an optical form that one of skill in the art would "believe likely to be biologically inactive" (Applicant's remarks, p.12). This is not persuasive. As discussed *supra*, the compounds of Kyle et al. are, in fact, both structurally and stereochemically identical to those presently claimed. In view of the fact that Applicant fails to claim (or even disclose in the accompanying specification) a particular optical isomeric configuration (either L- or D-), Applicant's attempt to patentably distinguish the instantly claimed compounds over that of Kyle et al. by asserting a different optical isomeric configuration than that claimed is clearly not persuasive because the claims fail to recite such a limitation.

Moreover, even if Applicant had claimed a particular optical isomer (i.e., the "L" isomer as Applicant alleges), the teaching of a D-configuration in Kyle et al. would have reasonably suggested the

"L" isomer as well, since one of ordinary skill in the art would have readily recognized the existence of one or more chiral carbons within the compound itself, which would, thus, be suggestive of more than one optical isomer. In view of this recognition, the skilled artisan would also have appreciated a potential difference in biological activity between the "D" and "L" isomers, such that one may be considered slightly more active than the other (see *In re Adamson and Duffin* as cited above). However, the fact that Applicant may "believe" that a "D" configuration is biologically inactive compared to an "L" configuration (and, according to Applicant, would not suggest use of the "L" isomer) is Applicant's own personal opinion and is unsupported by any teaching or evidence in the art. Accordingly, as held in *In re Schulze*, the arguments of counsel (or, in this case, the opinions of counsel) are insufficient to take the place of evidence in the record and are properly found unpersuasive.

For these reasons, and those set forth at pages 6-8 of the previous Office Action dated February 26, 2007, rejection of claims 11-12 and 14 remains proper and is **maintained**.

Conclusion

Rejection of claims 11-12, 14, 17 and 26 is proper and is maintained.

Claim 13 is **objected** to for depending upon a rejected base claim.

Claims 15-16 and 18-25 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor. Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application

Information Retrieval (PAIR) system. Status information for published applications may be obtained

from either Private PAIR or Public PAIR. Status information for unpublished applications is available

through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer

Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR

CANADA) or 571-272-1000.

Leslie & Royds Patent Examiner

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September 6, 2007

ARDIN H. MARSCHEL

SUPERVISORY PATENT EXAMINER